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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,817	09/17/2003	Harry A. Dugger III	3633-038-999	4051

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DICKSTEIN SHAPIRO LLP
1825 EYE STREET NW
Washington, DC 20006-5403

EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,817	DUGGER, HARRY A.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/07/07 has been entered.

Receipt is acknowledged of Amendments and Remarks filed on 02/07/07. Claims 22-13 and 29 have been amended, while claims 1-21 have been canceled. Accordingly claims **22-29** are pending and under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deihl (WO 9413280) in view of Fassberg et al (EP 0656206A1) and further in view of Kanios et al (5,719,197).

Deihl teaches a **sprayable analgesic** composition comprising an analgesic compound which is absorbed into the bloodstream through the **buccal mucosa** and a pharmacologically acceptable liquid carrier. In a preferred embodiment the active agent is ibuprofen and the liquid carrier is **aqueous ethanol** (see page 3). The formulation may also contain other ingredients such

as surfactants, humectants, **flavoring agents**, etc (see page 4). The table in example I shows the concentration ranges of each ingredient. Deihl fails to disclose other suitable active agents for the said formulation, or the use of other solvents including polyethylene glycol and non-polar solvent.

Fassberg discloses aerosol, formulations for oral or nasal administration, which comprise a medicament, an excipient, propellant and optionally surfactants. The suitable excipients include **alcohols, polyethylene glycols, short chain fatty acids**, etc (see page 3). Fassberg discloses that any pharmaceutically active agent which can be delivered by oral or nasal inhalation may be used. Examples include antihistamines, antiallergics, analgesics, antibiotics, steroids, bronchodilators, etc (page 5, lines 42-50).

Kanios teaches compositions and methods for topical administration of pharmaceutically active agents. Topical administration means a direct contact of the formulation with tissue, such as skin or membrane, particularly the oral or **buccal mucosa** (col. 1, lines 29-59).

Kanios discloses that the composition comprises a therapeutically effective amount of at least one pharmaceutically **active agent**, a pharmaceutically acceptable **solvent** for the active agent (col. 2, lines 22-28). The solvent is preferably a polyhydric alcohol such as polypropylene glycol, ethylene glycol, also solvents including fatty acids such as oleic acid, as well as fatty esters or alcohols. The solvent is present in an amount from about 20 to 50 weight percent based on the total weight of the composition (col. 4, lines 1-49; col. 5, lines 24-66). The concentration of the solubilized active agent can range from **1 to 50%** by weight (col. 8, lines 1-9). The

acceptable carrier is intended to be any suitable finite or non-finite carrier including liquids, semi-liquids or solid carriers. Thus the active agent may be admixed with carriers such as spray-solution or any non-finite carrier known in the art for delivery of active agents (col. 8, lines 54-67). Other additives may be incorporated into the formulations such as flavorings (col. 10, lines 48-56).

Kanios discloses that pharmaceutically active agents suitable for such formulation include antibacterials, antiparasitics, anticonvulsants, antidepressants, antidiabetics, antifungals, antihistaminics, anti-inflammatories, antineoplastics, antipsychotics, diuretics, antivirals, sedative/hypnotics, etc. Specific examples of actives include cephalosporines, penicillin, macrolides, lidocaine, mepivacaine, propofol, ipratropium, amantadine, diazepam, pregabalin, primidone, clozapine, chlorpromazine, haloperidol, amitryptiline, buspirone, chlorzoxazone, clozapine, cyclobenzaprine, interferon beta, estradiol, nimodipine, tacrine, carbidopa, acetylcholine, epinephrine, phenytoin, pergolide, doxepine, clomipramine, zolpidem, amphetamine, dextroamphetamine, methylphenidate, sumatriptan, pemoline, mazindol, desipramine, flumazenil, mesoridazine, etc (columns13-31).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of formulations for buccal mucosal administration of Diehl, to have looked in the art for other specific solvents suitable for spray formulations of liquid carriers, as taught by Fassberg et al, with reasonable expectations of successfully preparing suitable formulations for various therapies. Furthermore it is obvious to

one of ordinary skill in the art to have substituted any suitable active agent for the analgesics of Diehl's buccal spray formulations claimed as taught by Kanios et al.

Claims **22-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al (WO 9303751) in view of Physicians' Desk Reference.

Fu teaches compositions and methods for the sublingual or **buccal** administration of therapeutic agents. The compositions comprise a therapeutic agent dissolved or dispersed in a carrier which comprises a **solvent**, an optional cosolvent, and an oral mucosal membrane transport enhancing agent. The solvent comprises from about 50% w/v to about 95% w/v of the carrier of a non-toxic alcohol. Non-alcohols useful in the said formulations include ethanol, isopropanol, stearyl alcohol, propylene glycol, polyethylene glycol and the like. Most preferred alcohol is ethanol. The cosolvent may be **water** (page 4, lines 12-26). Essential or volatile oils such as peppermint oil, spearmint oil, menthol, etc, are added in a concentration of between about 1 and 5% w/v (page 5, lines 4-10). The said liquid compositions are formulated in a **liquid spray** or a liquid drop (page 6, lines 1-2). Fu et al lacks teachings on specific active agents.

Physicians' Desk Reference teaches specific active agents for therapeutic use such as anti-bacterial agents solutions for injection for treating infections.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of formulations for buccal mucosal

administration of Fu et al, to have looked in the art for other specific active agents suitable for spray formulations of liquid carriers, as taught by Physicians' Desk Reference, with reasonable expectations of successfully preparing suitable formulations for various therapies. Furthermore it is obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents of Fu et al's buccal spray formulations as taught by Physicians' Desk Reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **22-29** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,110,486 in view of Physicians' Desk Reference. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the reference

claims. In other words, claims **22-29** are generic to all that is recited in claims 1-9 of U.S. Patent No. 6,110,486. Specifically, the buccal spray compositions of both applications are substantially the same except for the active agents included in the compositions. Thus it would have been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of U.S. Patent No. 6,110,486 as taught by Physicians' Desk Reference.

Claims **22-29** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,676,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the reference claims in view of Kanios et al. In other words, claims **22-29** are generic to all that is recited in claims 1-2 of U.S. Patent No. 6, 676,931. Specifically, the buccal spray compositions of both applications are substantially the same except for the active agents included in the compositions. Thus it would have been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of U.S. Patent No. 6,676,931 as taught by Kanios et al.

Claims **22-29** are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims of co-pending Application No. 09/537,118 in view of Kanios et al. The double patenting rejection is proper because the examined claims and the reference claims are substantially the same. The difference is that claims of the co-pending Application '118 recite different active agents. Kanios et al discloses that almost any active

agent can be used in the topical formulations. Thus it would have been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of co-pending Application No. 09/537,118 as taught by Kanios et al.

This is a provisional obviousness-type double patenting rejection.

Claims **22-29** are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 30-40 and 56-76 of co-pending Application No. 10/230,086 (US 20030095927) in view of Kanios et al. The double patenting rejection is proper because the examined claims and the reference claims are substantially the same. The difference is that claims of the co-pending Application '086 recite different active agents. Kanios et al discloses that almost any active agent can be used in the topical formulations. Thus it would have been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of co-pending Application No. 10/230,086 as taught by Kanios et al.

This is a provisional obviousness-type double patenting rejection.

Claims **22-29** are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31, 64-91 and 124-134 of co-pending Application No. 10/230,060 (US 20030077227). The double patenting rejection is proper because the examined claims and the reference claims are substantially the same. The difference is that claims of the co-pending Application '060 recite different active agents. Kanios et al discloses that almost any active agent can be used in the topical formulations. Thus it would have

been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of co-pending Application No. 10/230,060 as taught by Kanios et al.

This is a provisional obviousness-type double patenting rejection.

Claims **22-29** are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-19, 45-59 and 84-85 of co-pending Application No. 10/230,085 (US 20030095926). The double patenting rejection is proper because the examined claims and the reference claims are substantially the same. The difference is that claims of the co-pending Application '085 recite different active agents. Kanios et al discloses that almost any active agent can be used in the topical formulations. Thus it would have been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of co-pending Application No. 10/230,086 as taught by Kanios et al.

This is a provisional obviousness-type double patenting rejection.

Claims **22-29** are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims of co-pending Application Nos. 10/230,072 (US 20030190286); 10/230,059 (US 20030185761); 10/230,084 (US 20030095925); 10/230,075 (US 20030077229); 10/230,073 (US 20030077228); 10/834,815 (US 20050002867); 10/671,708 (US 20050180923); 10/671,717 (US 20040136914); 10/671,709 (US 20050163719); 10/671,719 (US 20040136915); 10/671,710 (US 20040136913); 10/671,715 (US 20040265239); 10/671,720

(US 20040141923); 10/671,708 (US 20050180923); 10/230,080 (US 20030082107) in view of Kanios et al. The double patenting rejection is proper because the examined claims and the reference claims are substantially the same. The difference is that claims of the co-pending Applications recite different active agents. For example, Application 10/230,075 recites active agents such as anti-arrhythmics, anti-hypertensives, heart regulators, vasodilators, etc. Application 10/230,059 recites active agents such as anti-opioids, anti-migraines, pain control agents, etc. Application 10/230,080 recites active agents such as anti-bacterials, antifungals, antiparasitics, etc. It is also noted that many such classes of active agents are common or overlap with the agents of the instant application. Kanios et al discloses that almost any active agent can be used in the topical formulations. Thus it would have been obvious to one of ordinary skill in the art to have substituted any suitable active agent for the active agents recited in claims of the co-pending Applications cited above, as taught by Kanios et al.

This is a provisional obviousness-type double patenting rejection.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

1) Oguri et al (JP 02-026661) teaches formulations for aerosol delivery comprising an active agent and a liquid carrier. Suitable active agents include analgesics and carrier formulations include polar and non-polar solvents and other agents. Carrier formulations may comprise a mixture of a polar and a non-polar solvent. Polar solvents include water, alcohols

such as ethyl alcohol, propylene glycols. Non-polar solvents include hydrocarbons or halogenated hydrocarbons are suitable. Menthol is one of flavors used.

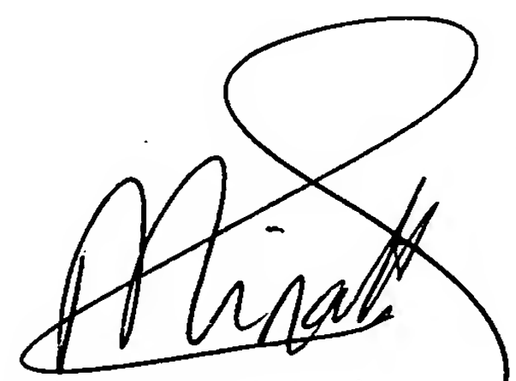
2) Kim (6,143,329) teaches aqueous-based pharmaceutical compositions comprising an active agent such as triamcinolone, purified water, Polysorbate and dextrose (see example 1). The said formulations are placed in a spray bottle for delivery to the surface of mucosa.

Applicant's remarks filed on 02/07/07 have been considered. New grounds of rejections have been applied.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mina Haghighatian
Patent Examiner
March 29, 2007